

Safety Data Sheet

European Format

Pristig Tablets

Preparation Date 09-Jan-2007 Revision Date 14-Aug-2008 Revision Number 4

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Product NamePristiq TabletsCommon NameNot availableChemical NameNot applicableSynonymsNot available

Product Use Pharmaceutical product

Classification Antidepressant Central Nervous System Selective Serotonin Reuptake Inhibitors /

Norepinephrine Reuptake Inhibitor

Supplier Wyeth

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Emergency Telephone Number Chemtrec USA, Puerto Rico, Canada 1-800-424-9300

Chemtrec International 1-703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	EC No.	Composition	Classification
Inactive Ingredients	Not applicable	Not applicable	Remainder	Not applicable
Desvenlafaxine Succinate	93413-62-8	Not available	50-200 mg/tablet	R36Irritating to eyes
Monohydrate				

3. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Pharmaceutical tablet Physical State Solid Odor Odorless

Potential Physical Hazards Powders and solids are presumed to be combustible.

Potential Health Effects

Eyes May cause mechanical eye irritation

Skin Not available Inhalation Not available

Ingestion The most common effects may include weakness, headache, anorexia, constipation, dry

mouth, nausea, dizziness, libido decrease, somulence, upper respiratory infection, yawning,

sweating, abnormal ejaculation/orgasm, anorgasmia, dysmenorrhea and impotence.

Therapeutic Target Organ(s) Central nervous system

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects See Section 12

4. FIRST AID MEASURES

Eye Contact In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek

medical advice.

Skin Contact Take off contaminated clothing and shoes immediately. Wash off immediately with soap and

plenty of water. If skin irritation persists, call a physician.

Inhalation Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist,

call a physician.

Ingestion If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never

give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties Not flammable

Extinguishing Media

Suitable Extinguishing Media

Unsuitable Extinguishing

Media

Use water spray, foam, dry chemical or carbon dioxide.

Do NOT use water jet.

Fire Fighting Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with

water spray. In the event of fire and/or explosion do not breathe fumes.

Hazardous Combustion Products Carbon oxides, nitrogen oxides.

Protective Equipment and Precautions for Firefighters

In the event of fire, wear self-contained breathing apparatus and special protective equipment

for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions Prevent product from entering drains. Local authorities should be advised if a significant spill

cannot be contained.

Methods for Containment Not available

Methods for Cleaning up

Take up mechanically and collect in suitable container for disposal. Clean contaminated

surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling For personal protection see Section 8. Handle in accordance with good industrial hygiene and

safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls Apply technical measures to comply with the occupational exposure guideline. Local exhaust

ventilation is needed for limited open handling or where aerosols may be generated.

Personal Protective Equipment

Eye/face Protection Skin Protection Respiratory ProtectionProvide eye protection based on risk assessment.

Wear nitrile or latex gloves. Wear protective garment.

Base respirator selection on a risk assessment.

General Hygiene Considerations

When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands

before breaks and at the end of workday.

Other Limit access to only personnel trained in the safe handling of this material Consult a health and

safety professional for specific PPE, respirator, and risk assessment guidance

9. PHYSICAL AND CHEMICAL PROPERTIES

AppearancePharmaceutical tabletPhysical StateSolidColorVariousOdorOdorless

Odor Threshold Not available

pH Not applicable

Specific GravityNot applicableWater SolubilitySoluble in waterSolubilityNot applicableEvaporation RateNot applicablePartition CoefficientNot availableVapor PressureNot applicable

(n-octanol/water)

Boiling PointNot applicableAutoignition TemperatureNot applicableFlash PointNot applicableMelting PointNot available

Flammability Limits in Air

Explosion Limits

Upper Not applicable
Upper Not applicable

cable Lower Not applicable Lower Not applicable

10. STABILITY AND REACTIVITY

Chemical Stability Stable at room temperature.

Conditions to Avoid No data available

Materials to Avoid No materials to be especially mentioned.

Hazardous Decomposition ProductsNone under normal usePossibility of Hazardous ReactionsNone under normal use

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Desvenlafaxine Succinate Monohydrate

LD50 OralNo data availableAcute Dermal IrritationNo data availablePrimary Eye IrritationNo data availableSensitizationNo data available

Multiple Dose Toxicity

Desvenlafaxine Succinate Monohydrate

No Toxicologic Effect No data available Dose/Species/Study Length:

Maximum Tolerated Dose (MTD), Oral

Desvenlafaxine Succinate Monohydrate

CarcinogenicityNo data availableGenetic ToxicityNo data availableReproductive ToxicityNo data availableDevelopmental ToxicityNo data available

Desvenlafaxine Succinate Monohydrate

Target Organ(s) of Toxicity No data available

12. ECOLOGICAL INFORMATION

Chemical Fate Information Not available

Ecotoxicity

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

15. REGULATORY INFORMATION

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

16. OTHER INFORMATION

Prepared By Wyeth Department of Environment, Health & Safety

Format This MSDS was prepared in accordance with Directive 2001/58/EC.

List of ReferencesProduct Package InsertRevision SummaryChanges to Section 1

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End of MSDS